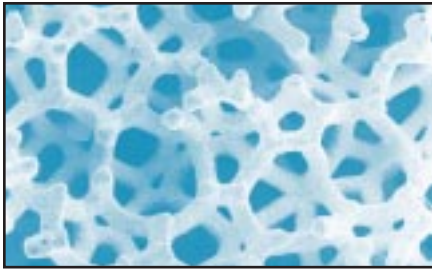


## IMPLANTS MEAN MORE SUPPORT FOR WEAKENED SPINES

*A synthetic cellular material once used to insulate rocket nozzles is now restoring mobility and comfort to the lives of spinal implant patients.*



■ Hedrocel® cellular materials (pictured above) are readily compatible with natural bone.



■ Pictured above is the Hedrocel® Acetabular Cup, a commercially available device used in total hip replacements for patients suffering from hip arthritis.

The human spine may be resilient, but it is not impervious to harm. Damage can result from trauma when the tissues between the vertebrae of the spine are compressed, which is what happened to actor Christopher Reeve during his tragic horseback riding accident. Less obvious damage can result from bone diseases such as osteoporosis and arthritis, which gradually destroy spinal bone mass during the aging process.

Ultramet, Inc. (Pacoima, CA), has developed a synthetic cellular biomaterial that in some cases of trauma and disease could help shore up the spine, preventing further injury. With its relatively high strength and porous structure, the biomaterial can act as a biocompatible replacement for damaged vertebral bodies and as a facilitator for spine fusion. In either case, it can greatly reduce the pain typically associated with bone and between-the-bone tissue loss, thus improving the quality of life for those with debilitating spinal problems caused by accidents or bone degeneration diseases.

**Similar to cork.** The biomaterial is an open-celled lattice that mimics the properties of, and is compatible with, bone. It appears similar in structure to natural materials such as coral and cork, but it is made stronger with tantalum—the most corrosion-resistant, biologically acceptable metal available today. The biomaterial was derived from a BMDO SBIR project to develop synthetic cellular foams that could serve both as insulators and kinetic energy absorbers. BMDO funded the materials development to produce insulation technology for components inside rocket nozzles.

Implex Corporation (Allendale, NJ) has licensed and further developed this biomaterial for use in many musculoskeletal applications, including the human spine. Called Hedrocel®, the biomaterial can be used for permanent spinal applications. For example, it can be implanted between two vertebrae, providing immediate structural support for the spinal column. Left alone, it allows bone from the vertebrae above and below to gradually infiltrate its pores. This bone will gradually join and form a true bony fusion across the whole joint. This fusion reduces the possibility of pain from compressed spinal nerves.

The company considers Hedrocel to be a platform technology whose porosity and flexibility are well suited for spinal and other human body applications.

"The biomaterial's uniquely shaped, interconnecting pores result in a bulk volume porosity of greater than 80 percent," says Robert Cohen, Implex Corporation's vice president of product development. "Because of this high porosity, it has more room for bone to grow into the material, providing greater biological stability than conventional implant materials." Mr. Cohen adds that the material's flexibility "more closely resembles that of bone." Any spinal replacement material that is too stiff could cause undue load transmission to the spine because of the difference in flexibility characteristics. The bone will then remodel abnormally, creating another surgical challenge in the future.

Hedrocel implants can help patients with conditions such as osteoporosis when doctors feel that structural support is the most preferable option. According to the National Osteoporosis Foundation, osteoporosis is a major public health threat for more than 28 million Americans, 80 percent of whom are women. In the United States today, 10 million individuals already have the disease and 18 million more have low bone mass, placing them at increased risk for osteoporosis. The estimated national direct expenditures (hospitals and nursing homes) for osteoporotic and associated fractures is \$13.8 billion (\$38 million each day), and the cost is rising.

**Successful trials.** Implex's Hedrocel vertebral body replacement implants have been successfully used in 12 patients in Europe. Some patients had a lumbar (lower back) bone replaced, while others had a cervical (neck) bone replaced. In Europe and the United States, the Hedrocel cervical spacer implants have also successfully been used for cervical fusion by replacing the disc to allow the adjacent bones to grow together. Implex reports that the clinical results to date are positive and compelling.

Other Hedrocel products for joint replacement and fusion are emerging. In mid-1997, the company received U.S. Food and Drug Administration acceptance for a Hedrocel socket-side hip implant, which can be used in total replacements for patients with hip arthritis. These implants are currently being marketed. In addition, Implex is investigating the use of Hedrocel in cases requiring the fusion of joints in the human body; typically this procedure gives the patient a better quality of life after an accident or condition that makes bending a finger, wrist, or ankle too painful.

■ For more information, contact Robert Cohen via telephone at (201) 818-1800 or via E-mail at [robert.cohen@implex.com](mailto:robert.cohen@implex.com).



#### What Does It Mean to You?

Spinal implants can help relieve pain in persons suffering from degenerative spinal disease and may soon help restore motion to arthritic ball-and-socket joints in the hips.



#### What Does It Mean to Our Nation?

Spinal implants can help improve the quality of life for the 25 million Americans who either have or are at high risk for osteoporosis, which results in annual estimated costs of more than \$10 billion for direct medical treatment.

#### Tech Trivia

About how many vertebral fractures does osteoporosis lead to annually?

- A. 2,500
- B. 5,000
- C. 50,000
- D. 500,000

For the answer, see page 73.